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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/879,572

06/12/2001

Arlene I. Ramsingh

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7590

10/05/2006

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EXAMINER

CHEN, STACY BROWN

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 10/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/879,572	Applicant(s) RAMSINGH ET AL.	
	Examiner Stacy B. Chen	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 6-15, 17-22, 24-28, 30-36 and 54-73 is/are pending in the application.
- 4a) Of the above claim(s) 2, 19 and 54-72 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1, 18 and 73 is/are allowed, allowable. see 9/28/06
- 6) ☒ Claim(s) 3, 6-15, 17, 20-22, 24-28 and 30-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 June 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment filed July 11, 2006 is acknowledged and entered. Also acknowledged is the 4th declaration of Dr. Arlene Ramsingh, filed August 1, 2006, under 37 C.F.R. 1.132. Claims 1-3, 6-15, 17-22, 24-28, 30-36 and 54-73 are pending. Claims 2, 19 and 54-72 remain withdrawn from consideration, being drawn to non-elected subject matter.

The rejection of claims 74-78 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is moot. The following comments are made to clarify the record. Previously, the Office asserted that the limitation, "non-coxsackievirus", was not supported by the specification. It had been the Office's position that while the specification gave examples of epitopes of interest that are not coxsackievirus (page 19), the specification did not contemplate coxsackievirus chimerics, and thus their exclusion ("non-coxsackievirus") was not considered appropriate.

However, upon further review of the specification, particularly page 20, lines 7-8, epitopes of interest include those from coxsackievirus. The following is an excerpt from the specification at page 20, lines 7-8:

Preferably, the epitope is derived from HIV or coxsackievirus.

Since the specification does indeed contemplate coxsackievirus epitopes inserted into coxsackieviruses, the claims may appropriately state, as in claim 1 for example, "non-coxsackievirus". It is for this reason that the rejection is withdrawn.

Applicant's arguments have been carefully considered. Of note is the persuasive argument relating to *In re Johnson*, 194 U.S.P.Q. 187 (1997). As Applicant notes in their response, the inventor is deciding what bounds of protection to seek after having "discover[ed]

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during the course of prosecution that only a part of what they invented and originally claimed is patentable” (according to the Office’s position with regard to Caggana *et al.* (*J. Virol.*, 1993, 67:4797-4803) as prior art over chimeric coxsackieviruses). Therefore, since the specification contemplated chimeric coxsackieviruses, Applicant is entitled to carve the embodiment of chimeric coxsackieviruses out of the claimed invention.

It is for the same reason, that the rejection of claims 1, 3, 6-12, 18, 20-22, 24-27, 30-33 and 73 under 35 U.S.C. 102(b) as anticipated by Caggana *et al.* (*J. Virol.*, 1993, 67:4797-4803) is withdrawn. Caggana *et al.* fail to teach or suggest non-coxsackievirus chimeric constructs.

Claim Rejections - 35 USC § 112

Claims 3, 6-15, 17, 20-22, 24-28 and 30-36 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. It is apparent that coxsackievirus CB4-P is required to practice the claimed invention because it is a necessary limitation for the success of the invention as stated in the claims. As a required element it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. § 112, first paragraph, may be satisfied by a deposit of coxsackievirus CB4-P. See 37 CFR 1.802. One cannot practice the claimed invention without the specifically named CB4-P coxsackievirus strain. Therefore, access to coxsackievirus CB4-P is required to practice the

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invention. While the specification provides a method for obtaining a virus that is like CB4-P, the specification does not provide a repeatable method for obtaining *the* CB4-P without access to *the* CB4-P and it does not appear to be readily available material.

Deposit of coxsackievirus CB4-P in a recognized deposit facility would satisfy the enablement requirements of 35 U.S.C. 112., because the strain would be readily available to the public to practice the invention claimed, see 37 CFR 1.801- 37 CFR 1.809. In addition the identifying information set forth in 37 CFR 1.809(d) should be added to the specification.

Applicant's arguments have been carefully considered but fail to persuade. Applicant's substantive arguments are primarily directed to the 4th declaration of Arlene I. Ramsingh, filed August 1, 2006 under 37 C.F.R. 1.132. The declaration is addressed below. Preliminarily, the Office offers the following clarification on its position regarding "CB4-P". If Applicant wishes to claim a "class" of viruses that have the same properties and characteristics as CB4-P, then it is suggested that instead of using the laboratory designation "CB4-P", Applicant may claim the class of viruses by its characteristics, rather than a particular laboratory designation.

Response to Arguments

4th Declaration of Arlene I. Ramsingh

The declaration of Arlene I. Ramsingh, an inventor of the instant invention, filed August 1, 2006, has been considered.

- Point 1 : Dr. Ramsingh identifies herself as a co-inventor of the instant application and acknowledges that she is familiar with the USPTO's requirement for deposit of CB4-P.

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- Points 2 and 4: Dr. Ramsingh comments on the availability of the starting virus, JVB, available from the ATCC as accession number VR-184. Dr. Ramsingh states that the claimed viruses, CB4-P, can be made from CB4 (strain designation JVB). Dr. Ramsingh discusses the disclosed cloning strategies for practicing the invention.
- The Office does not dispute that viruses like CB4-P can be made from available materials. The use of the laboratory designation CB4-P requires accessibility to that one. If Applicant intends for the name “CB4-P” to simply represent a class of viruses, then the class of viruses must be claimed by their characteristics and not by a laboratory designation.
- Point 3: Dr. Ramsingh discusses the availability and significance of CB4-P sequence information. Dr. Ramsingh reiterates that half of the genome of CB4 has been sequenced and that that sequence is available from GenBank as Accession #S39291. Dr. Ramsingh asserts that this half sequence is all that is required to practice the claimed invention. In particular, Dr. Ramsingh states that the CB4-P variant is CB4 virus of the JVB strain, and that if one were to construct a CB4-P virus, the published half-sequence contains all of the information necessary. Dr. Ramsingh notes that the Office’s assertion that a single nucleotide substitution in the region encoding the non-structural protein would make it a different virus runs counter to what is accepted by those in the field and ignores concepts of genetic relatedness. Dr. Ramsingh notes that CB4-P is not a strain, rather, a variant of CB4. CB4-P and JVB are alternative names for the same viral strain.
- In response, the Office will not refer to CB4-P as a strain, rather, a variant of CB4. In the scientific field, it is acknowledged that “strains”, “variants”, etc. take on meanings that

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are different from those in field of law. From the perspective of the Office, CB4-P differs in nucleotide sequence from JVB, rendering CB4-P different from JVB. While this difference may not be of any significance to a scientist, from the perspective of law, one cannot call CB4-P, JVB, since they are simply not the same entity. If they were the same entity, then Applicant would be able to state in claim 3, "The recombinant attenuated coxsackievirus B4 virion of claim 1, which is CB4-P, deposited at the ATCC as accession number VR-184." If Applicant cannot state this, then CB4-P and JVB are not one and the same legally. If indeed CB4-P and JVB are one and the same, then the Office would consider an amendment that deletes all recitations of CB4-P, and replaces them with JVB, as deposited at the ATCC as accession number VR-184.

- The declaration skips to Points 9 and 10, although this is believed to be a typo. In Points 9 and 10, Dr. Ramsingh concludes that one would be able to arrive at the claimed invention based on the materials already publicly available.

Declaration of Steven Tracy

- Applicant points to the declaration of Steven Tracy filed May 26, 2005, previously considered. Applicant points to section 9 of the declaration as a reminder that one can practice the instant invention without access to CB4-P because all that is required is access to JVB, which is accessible.
 - In response, it is understood that the invention can be practiced with other CB4 viruses other than CB4-P. It is also understood that if one were to obtain CB4-P progeny, the sequences of the progeny are likely to be different from the original

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CB4-P. Nevertheless, the claims are specifically drawn to CB4-P. Without access to CB4-P, one would not be able to practice the invention as claimed because the claims recite, "CB4-P". Without access to CB4-P, one would not be able to obtain progeny of CB4-P. Therefore, the declaration of Dr. Tracy is inadequate to overcome the rejections of record.

Conclusion

Claims 1, 18 and 73 are allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Stacy B. Chen 9/28/06
STACY B. CHEN
PRIMARY EXAMINER